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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,033	02/28/2002	Jon S. Wilson	4798-06A(17.1)	5173
30166 7	590 10/11/2002			
WOMBLE CARLYLE SANDRIDGE & RICE PLLC 300 N. GREENE STREET SUITE 1900			EXAMINER	
			NICOLAS, FREDERICK C	
GREENSBOR	U, NC 2/401		ART UNIT	PAPER NUMBER
			3754	
			DATE MAILED: 10/11/2002	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/086,033	WILSON ET AL.				
Office Action Summary	Examiner	Art Unit				
	Frederick C. Nicolas	3754				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
1) Responsive to communication(s) filed on <u>08 A</u>	ugust 2002 .					
2a)⊠ This action is FINAL . 2b)□ Thi	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims						
4) Claim(s) 1-15 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5)⊠ Claim(s) <u>7-13</u> is/are allowed.						
6)⊠ Claim(s) <u>1-6,14 and 15</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement. Application Papers						
9) The specification is objected to by the Examine	•					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents	s have been received.					
2. Certified copies of the priority documents	s have been received in Applicat	ion No				
 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)				

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DETAILED ACTION

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- I- As to claim 1, the claimed limitation "a first end" as recited in line 8, and "a first end" as recited in lines 8-9, are vague and unclear because it is not clear if the claimed limitation in lines 8-9, "a first end" is the same as the claimed limitation noted in line 8 above. Applicant should restructure the claimed language to prevent double inclusion throughout the claims.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1,14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markel et al. (U.S 5,624,413).

Markel et al. discloses a method for inserting a multi-lumen catheter assembly into an area to be catheterized as best seen in Figure 1, the multi-lumen catheter assembly having a catheter tube (22) and (24), the tube has a proximal portion and a

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distal portion see Figure 1 for location, an attachable hub assembly (76) and (78) having a hub body (86) with a distal portion and a proximal portion see Figure 7 for location, the method comprises the steps of: making an incision (70) near the area to be catheterized, inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized, and creating a subcutaneous tunnel where a first end of the subcutaneous tunnel is near the incision near the area to be catheterized (column 7, lines 30-53) and as best seen in Figure 2, routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through a second end of the subcutaneous tunnel (column 7, lines 54-67 onto column 8, lines 1-8) and as best seen in Figure 2, attaching the proximal portion of the hub body to the distal portion of the catheter tube (column 8, lines 21-36). Markel et al. lacks the multi-lumen catheter assembly having a multi-lumen catheter tube.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the catheter tubes (22) and (24) of Markel et al. into a multi-lumen catheter tube, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S 164 (1983).

5. Claims 1,14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markel et al. (U.S 5,624,413) in view of Bates (U.S 4,772,268).

Markel et al. discloses a method for inserting a multi-lumen catheter assembly into an area to be catheterized as best seen in Figure 1, the multi-lumen catheter assembly having a catheter tube (22) and (24), the tube has a proximal portion and a

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distal portion see Figure 1 for location, an attachable hub assembly (76) and (78) having a hub body (86) with a distal portion and a proximal portion see Figure 7 for location, the method comprises the steps of: making an incision (70) near the area to be catheterized, inserting the proximal portion of the multi-lumen catheter tube into the area to be catheterized, and creating a subcutaneous tunnel where a first end of the subcutaneous tunnel is near the incision near the area to be catheterized (column 7, lines 30-53) and as best seen in Figure 2, routing the distal portion of the catheter tube through the subcutaneous tunnel beginning at the first end and exiting through a second end of the subcutaneous tunnel (column 7, lines 54-67 onto column 8, lines 1-8) and as best seen in Figure 2, attaching the proximal portion of the hub body to the distal portion of the catheter tube (column 8, lines 21-36). Markel et al. lacks the multi-lumen catheter assembly having a multi-lumen catheter tube. Bates teaches the use of having a multi-lumen catheter tube (10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the teaching Bates into the invention of Markel et al. by modifying the catheter tubes (22) and (24) of Markel et al. as such, in order to minimize the amount of incision to one instead of two different incisions into an area to be catheterized.

Allowable Subject Matter

6. Claims 7-13 are allowed.

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7. Claims 2-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Response to Arguments

- Applicant's arguments filed 8/8/2002 have been fully considered but are moot in 8. view of the new ground(s) of rejection. Any remaining arguments have been fully addressed in the above rejection.
- 9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the 10. examiner should be directed to Frederick C. Nicolas whose telephone number is (703)- Art Unit: 3754

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305-6385. The examiner can normally be reached on Monday - Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry C. Yuen, can be reached on (703) 308-1946. The fax phone number for the organization where this application or proceeding is assigned is (703)-308-7766.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0861.

FN

October 3, 2002

Supervisory Patent Examiner

Group 3700